Remarks/Arguments

The Claim Rejections/Objections

The Examiner has rejected Claims 1-3, and 13-15 under 35 U.S.C. 102(b) as being anticipated by Mikus, et al. (2002/0151967). The Examiner has rejected Claims 4 and 6 under 35 U.S.C. 103(a) as being unpatentable over Mikus, et al. (2002/0151967). The Examiner has rejected Claim 5 under 35 U.S.C. 103(a) as unpatentable over Mikus et al. in view of Frantzen (6,042,606). The Examiner has rejected Claims 7-12 under 35 U.S.C. 103(a) as unpatentable over Mikus et al. in view of Scarborough (5,928,238).

The Response

Applicant respectfully requests the Examiner to reconsider her rejection of independent Claims 1, 9 and 13, each of which have been amended to emphasize the distinctions between the present invention and Mikus. Claim 1, as amended herein, requires, inter alia, a hub with a grip portion and a collar, said hub having a sidewall bounding an axial hollow into which said mandrel extends, said collar coaxially received on said hub and having a tab extending at a distal end thereof, said tab having an inwardly directed surface facing a central axis of said collar, said collar moveable telescopically on said hub between a retracted position and a deployed position, said hub having a relief slot on an exterior surface of said sidewall external to said hollow, said relief slot having an outwardly directed surface facing away from a central axis of said hub, said relief slot formed in said sidewall proximate a distal end thereof, said relief slot positioned on said hub to align with said tab, such that said inwardly directed surface of said tab and said outwardly directed surface of said relief slot face each other with a spacing there between for accommodating a portion of the stent when said collar is in the deployed position, said tab capturing the stent proximate a proximal end thereof between said inwardly directed surface of said tab and said outwardly directed surface of said relief slot, said apparatus compressing the at least one protrusion when said mandrel is rotated relative to

said protrusion compressor while the stent is captured between said tab and said relief slot. Claims 9 and 13 have been similarly amended. The Mikus reference does not exhibit the above-described features.

Mikus is directed to a different type of apparatus that functions differently than the present invention and therefore has different structural features and functionality. More specifically, Mikus discloses a stent delivery apparatus for delivering a stent made from a shape memory alloy, e.g., nitinol (paragraph 0086). As descibed in Mikus, a stent made from this type of material will be soft and pliable at a lower temperature allowing it to be wrapped around an inner catheter 114 for delivery into a patient (paragraph 0093). While in the pliable martensite state, the stent is retained on the inner catheter by pull wires. The wrapped configuration may be maintained/adjusted by the relative rotation of a coaxial outer catheter 115, to which the other end of the stent is removeably attached via a pull wire, the other end being removeably attached to the inner catheter via a pull wire. Upon placement in the patient, heating of the stent causes a transition to the austentite state whereupon it reverts to a memorized, larger diameter configuration and the pull wires may be withdrawn (paragraphs 0097-0098).

In contrast, the present invention is directed to an instrument that is suitable for compressing a stent that is already in the expanded state prior to insertion in the patient (does not need to be in the martensite state for handling). The stent is of the type which has at least one enlarged coil at one end. The stent is placed on the instrument of the present invention with the enlarged coil proximate to a coil grasping mechanism that can grasp the coil near one end. The other portion of the coil is held by friction on the stent retention zone of a mandrel that may be turned relative to the coil grasping mechanism to wind the stent into a tighter configuration to enable insertion into a lumen. The present invention provides an apparatus that can be used to focus coiling and uncoiling to one end of the stent, i.e., the enlarged coil(s). This is done by frictionally engaging the stent at the stent fixation zone and then coiling/uncoiling the enlarged proximal coil(s) only. Moving the extreme proximal end of a stent relative to the

extreme distal end (as in Mikus) differs from moving the proximal end of the stent relative to where the stent first contacts the stent retention zone distally of the enlarged coil(s), because in the latter case, all coiling/uncoiling is focused on the enlarged proximal coil(s) rather than being distributed along the entire length of the stent.

As can be appreciated from the amended claims, the amendments describe structural and functional features of the present invention that are not present in Mikus and therefore should overcome the Examiner's latest rejections based upon Mikus. Nevertheless, since Mikus was cited in the outstanding office action against Claim 9, a claim that was previously indicated as being allowable over Mikus, based upon a "newly discovered interpretation" of Mikus, Applicant's attorney thinks that the Mikus reference and the Examiner's interpretation of same should be reviewed herein.

It appears to Applicant's attorney that the Examiner is interpreting one ambiguous portion of Mikus (FIG. 14) in a deliberately "naive" (less than fully informed) manner, by viewing it in isolation from the remainder of the specification and drawings (which would serve to eliminate the ambiguity and eradicate the proffered "naive" interpretation. This "naive" viewpoint is available due to the fact that FIG. 14 was poorly drawn (notwithstanding that the lines are straight and the reference numbers neatly written). This raises the issue as to whether it is necessary and proper to consider FIG. 14 in the context of the specification of Mikus, or, as the Examiner appears to suggest, that it is proper to consider FIG. 14 out of context, for what it shows in isolation. Applicant's attorney respectfully submits that the contextural approach is the correct approach - at least in the present case.

MPEP section 2125 instructs that drawings can be used as prior art and can anticipate claims if they clearly show the structure which is claimed, *In re Mraz*, 455 F.2d 1069 (CCPA 1972). However, the picture must show all the claimed features and how they are put together, *Jackmus v. Leviton*, 28 F. 2d 812 (2d Cir. 1928). In interpreting drawings, the drawings must be evaluated for what they reasonably disclose and suggest to one of normal skill in the art, *In re*

Aslanian, 590 F. 2d 911 (CCPA 1979). In this particular instance FIG. 14 does **not clearly show** the structure that is claimed, **nor all the claimed features, nor how they are put together**. In fact, when viewed from the standpoint of someone normally skilled in the art, FIG. 14, taken by itself, does not even provide an enabling depiction of the invention disclosed in the Mikus application, let alone the present invention.

More particularly, in isolation, FIG. 14 of Mikus shows a compound elongated apparatus having a central barrel 116 to which is attached at one end a generally perpendicular, generally rectangular flange 119 that has a symmetrical compound bending as it projects in opposite directions from one end of the central barrel. A generally flat, thin, blade-like member extends out of one end of the barrel and has a slot at one end that together with an angled cut and a rounded portion at the tip form a sharp point pointing at right angles to the overall length of the blade member 115. The blade member has portion that is formed into a semicircular cross-sectional shape that extends out of the barrel 116 near the flange 119. The semi-circular portion of the blade member 115 appears to be offset from the other side of the blade portion 115 and either attaches to or extends into a disc-shaped member 118. An unidentified member or surface is depicted in dotted lines and appears to indicate a semicircular surface behind or within the disc-shaped member 118. A generally cylindrical or semi-cylindrical member 137 extends from or behind the disc-shaped member 118. A small blade-shaped member (no reference number) extends parallel to the member 137, such that a spacing exists between the blade-shaped member and the member 137.

A small disk 114d is attached to a small-diameter cylindrical member (no reference number). The small-diameter cylindrical member is much smaller in diameter than the barrel 116. A thin cylindrical member with a plurality of segments is loosely disposed around the end of the small diameter cylindrical member. (Of course, Applicant's attorney and the Examiner both know that the thin cylindrical member is a depiction of a stent because we have already read the specification.) The thin cylindrical member could be viewed as a coil with individual

coils that either overlap or are in continuous side contact or as a coil with spacing between the individual coils equaling the width of the individual coils. No matter whether the individual coils are considered overlapping, closely spaced or widely spaced, the end of the coil near the blade 115 is aligned with the notch in the blade 115. Given that the notch appears to have a larger width than the width of the coil, and that there appears to be a significant spacing between the coil and the blade 115, the coil appears to be maintaining itself in a compact configuration without contacting or interacting with the blade 115. It is not evident what is holding the coil on the thin cylindrical member, since the coil has a significantly larger diameter than the thin cylindrical member.

Without protracting this type of analysis further, one can see that FIG. 14 by itself does not adequately disclose the relationship between the various portions of the apparatus depicted therein or how the apparatus works. It does not disclose what elements are fixedly or moveably connected to other elements, nor why the specific parts have the specific shapes they may have, e.g., what is the purpose of the sharp point on the end of the blade 115?, etc. One would therefore expect that a normally skilled artisan in the field of medical devices who had this reference in their hands and who was interested in learning what the device was, how it was made and how it worked, would inevitably turn the page from FIG. 14 to refer to the specification and the other drawing views for the missing information. When the normally skilled artisan examines this additional material, he or she would then clearly see the relationship between FIGS 12-20 and would come to appreciate that FIG. 14 is just not drawn well enough to explain the apparatus depicted therein. They would appreciate that FIG. 14 inaccurately depicts the relationship between the stent and the "hook". Most likely, the normally skilled artisan would see how the rest of the specification of Mikus cures and resolves the ambiguities and misleading aspects of FIG. 14.

Taking the contextural approach, the approach that the normally skilled artisan would take, one can see as a starting point, that the Brief Description of the Drawings portion of Mikus

indicates that FIGS. 12-14 all illustrate the same apparatus (paragraphs 0041-0043). Differences and inconsistencies therebetween call out for their reconciliation, e.g., by reviewing the specification. One can further readily appreciate that FIGS 15-20 illustrate use of the apparatus illustrated in FIGS. 12-14 (paragraphs 0095 - 0099 - same apparatus illustrated with same reference numbers).

FIG. 13 and 14 of Mikus and the relevant sections of the Mikus specification, e.g., paragraphs 0087-0098 disclose that an outer catheter 115 cooperates with an inner catheter 114 for controlling the position and conformation of a stent 110 positioned about the inner catheter 114. In Mikus, the stent is retained on the inner catheter 114 by a pull wire 125 extending through a lumen 124 in the wall of the inner catheter 114 and through a hole 127 proximate the distal end of the stent 110. The proximal end of the stent 110 also has a hole 134 accommodating a pull wire 132 for holding the stent in association with the outer catheter 115. As noted in a prior response, FIGS 2 and 3 of U.S. Patent No. 6,413,269 to Bui et al. ("Bui"), a related application, appear to show this arrangement more clearly.

In Mikus, the fixation of the ends of the stent 110 by the respective pull wires 125, 132 permits the stent 110 to be coiled or uncoiled by the relative rotation of the inner catheter 114 and the outer catheter 115. Further, the stent 110 may be released from the delivery catheter 111 by pulling the wires 125, 132 from the holes 127, 134. The structure which the Examiner has referred to as a "hook" that is shown in FIG 14 is also shown in FIG. 13, i.e., in the area identified by reference number 133. Mikus identifies 133 as the "distal extension of the pull wire lumen 131 beyond the annular recess 130". Mikus apparently does not provide a name or a reference number for the "hook" noted by the Examiner, the reference number 133 referring to a lumen through the "hook".

A close review of Mikus reveals that the "hook" is a continuation of the outer catheter 115 (around the recess 130) that provides a support for the pull wire 132 after it passes through the hole 134 in the proximal end of the stent, i.e., in the distal extension 133 of the pull wire

lumen 131. As shown in FIG. 13 and described in paragraphs 0090 and 0091, the "hook" has an outer diameter approximating the outer diameter of the stent 110 when the stent 110 is tightly wound on the inner catheter 114. As a result, the "hook" inserts between the proximal end of the stent 110 and the immediately adjacent proximal coil of the stent 110. This is consistent with it's function of receiving the pull wire 132, i.e., within lumen extension 133. Due to a shared diameter, the "hook" in Mikus must be disposed between the coils and therefore can not over-ride them. As a result, the "hook" of Mikus, unlike the tab of Claim 1, is not used to over-ride or clamp the stent as the Examiner has suggested.

Mikus clearly teaches away from use of the "hook" as a member for pressing the stent toward the axis of the inner catheter due it's substantially different and specialized structure and functional relationship relative to the stent. The "hook" has the same outer diameter as the stent and therefore can not over-ride or press the stent inwardly. In addition, the overall functionality of the Mikus device is incompatible with the present invention as claimed in the independent claims and suffers from the limitations of the prior art. Mikus requires lumens 124, 131 to be formed in the walls of the inner and outer catheters 114, 115 and holes 127, 134 in the ends of the stent 110 to pass the pull wires 125, 132. The pull wires are threaded though the lumens and through the holes in the ends of the stent and then through a further extension of the lumens beyond each of the stent holes. The pull wires constrain the extreme ends of the stent to control coiling and uncoiling of the stent (via relative rotation of the inner and outer catheters) and allow the stent to be released when the pull wires are drawn back, out of the holes in the stent.

From the foregoing, one can conclude that a reasonable consideration of Mikus (that would allow FIG. 14 to be comprehensible to the normally skilled artisan) would lead to the conclusion that it does not anticipate the features of the claimed invention, either as previous claimed or as now more specifically claimed in the amended independent claims.

The features of previously presented Claim 4 pertaining to the frictional engagement between the mandrel/means for holding and the stent have been incorporated into each of the independent claims. In rejecting Claim 4 as previously presented, the Examiner contends that it would be obvious to modify Mikus to have a stent fixation zone with a diameter greater than the lumen of the stent. Applicant's attorney respectfully disagrees in that Mikus describes wrapping the stent around the inner catheter when it is in a soft and flexible state. Since the stent is formed about (conforms to) the diameter of the inner catheter, there is no way for the catheter to have a greater diameter than the stent. By definition, the stent must always have an inner diameter that is equal to or greater than the inner catheter. As a result, Mikus is incompatible with the concept of having a stent with a lumen having a smaller diameter than the inner catheter and teaches away from that condition.

The contention that a mere change in size is obvious, is inapplicable here since whatever size is chosen for the Mikus inner catheter, the stent formed about it will be of an equal or great diameter. Furthermore, the claimed interaction between the stent and the stent retention zone provides an additional functional attribute not present in Mikus.

The Examiner contends that Mikus shows a relief slot, a feature claimed in each of the independent claims (in Claim 13 it is referred to as an "opposable slot"), viz., the "distal opening at the end of the tube 116 shown in FIG. 13". Applicant respectfully submits that interpreting the distal opening of tube 116 in Mikus as a "relief slot" is not reasonable or proper. MPEP section 2111 indicates that during examination, the pending claims must be given their "broadest reasonable interpretation consistent with the specification." Further, that the broadest reasonable construction is to be made "in light of the specification as it would be interpreted by one of ordinary skill in the art.", *In re American Academy of Science Tech. Center*, 367, F.3d 1359 (Fed. Cir. 2004). The Examiner's interpretation of the lumen opening of a tube as a "relief slot" is incompatible with standard useage and would not be understood by one of normal skill in the art on its face. Even the Examiner uses the conventional terminology "distal opening at the

end of the tube 116" to identify the element referred to. Besides being unconventional, the Examiner's interpretation of element 116 as a "relief slot" is clearly incompatible with the use of that term in the specification of the present application.

In light of the foregoing, Applicant respectfully submits that the Examiner has failed to show either the claimed tab or relief slot, their cooperation or functionality in the Mikus reference. To remove any doubt, the independent claims have been amended to more specifically recite these features without introducing any new matter. Accordingly, Claims 1, 9 and 13 should now be allowable.

The Dependent Claims

Because each of the independent claims distinguish over the references cited, all claims depending therefrom should also be patentable. The dependent claims also recite additional features which further distinguish over the references. For example, Claim 7 recites that the collar is restrained from rotating relative to the grip portion by a pin extending therethrough and into an elongated slot in the hub, the slot and pin constraining the collar to telescopic movement on the hub along a length of travel limited by the slot. The Examiner has rejected Claim 7 on obviousness grounds utilizing Mikus as the base reference and U.S. Patent No. 5,928,238 to Scarborough et al as a secondary reference. The Examiner suggests that Scarborough "discloses a collar (322) restrained from rotating relative to said grip portion (the proximal end of part 324) by a pin (326) extending therethrough and into an elongated slot (328) in said hub (324)" constraining the collar to telescopic movement on said hub along a length of travel limited by said slot.

In fact, the "collar (322) " is described in the Scarborough patent as an "inner rod member 322" and the element 324 is not a "grip portion" but rather, a "coaxial outer plunger sleeve" in the patent. The foregoing recharacteriziation of the elements recited by the Examiner in making the rejection again raises the rules recited in MPEP section 2111, indicating that during examination, the pending claims must be given their "broadest reasonable interpretation

consistent with the specification." Further, that the broadest reasonable construction is to be made "in light of the specification as it would be interpreted by one of ordinary skill in the art.", *In re American Academy of Science Tech. Center*, 367, F.3d 1359 (Fed. Cir. 2004).

In rejecting Claim 7, the Examiner appears to be interpreting the claim term "collar" far too broadly, such that it encompasses an element that has no similarity whatsoever to what anyone (including those with normal skill in the art) normally thinks of as a "collar". In a similar manner, the "coaxial outer plunger sleeve" of the Scarborough patent is in no sense a "grip portion" as recited in Claim 7. The Scarborough patent pertains to a bone dowel cutter and has nothing to do with stents or apparatus for working with stents. All these factors indicate that the Examiner has drastically repurposed and reinterpreted a plurality of elements in a patent that is unrelated to the structure, function and purpose of the claimed invention.

Having thus artificially isolated these elements with no motivation other than hindsight, the Examiner has further used hindsight to merge them with the apparatus of Mikus based upon an implausible motivation. More particularly, the Examiner suggests that the normally skilled artisan would be motivated to replace the removeable collet 137 of Mikus with the repurposed slot/pin mechanism of Scarborough to prevent accidental deployment of the stent. The stated purpose of the collet 137 in Mikus is to "lock the inner catheter and the outer catherters (SIC) longitudinally in relation to each other until longitudinal movement is desired." This is not the purpose or function of the pin and slot arrangement in Scarborough, which, even if re-engineered to be incorporated in some manner in the Mikus device, would not provide a removeable lock feature, so that the proposed motivation for making the combination appears defective. For each and all of the foregoing reasons, the proposed combination does not appear to be obvious and therefore Claim 7 should be patentable.

Claim 10 specifies a ball and detent interface disposed between the grip portion and the knob for controlling relative motion. While the Examiner notes that ball and detent interfaces are well known, the Examiner has not provided any references to show that a ball and detent

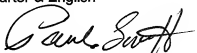
interface would be known for use in this particular application or why it would be obvious for a normally skilled artisan to employ a ball and detent interface at the particular place and purpose as claimed in Claim 10.

Applicants' attorney respectfully requests reconsideration and allowance of the amended claims.

No fees are thought to be required for this Response, however, if any fees are due as a result of this Response, the Examiner is authorized to charge them to Deposit Account No. 503571.

Respectfully Submitted,

McCarter & English



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